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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,502	04/11/2006	Traci Jo Barron	X-16327	3927

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EXAMINER	
ANDERSON, MICHAEL J	
ART UNIT	**PAPER NUMBER**
3767	

NOTIFICATION DATE	DELIVERY MODE
11/16/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/575,502	BARRON ET AL.	
	Examiner	Art Unit	
	Michael J. Anderson	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/11/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The references cited have been considered, and will be listed on any patent resulting from this application since they were provided on a separate list in the Information Disclosure Statement (IDS) Form PTO/SB/08 in compliance with 37 CFR 1.98(a)(1).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Burroughs (US Patent No. 6,221,046 B1) (Hereafter, Burroughs) and Balkwill (US Patent No. 5,279,586) (Hereafter, Balkwill) as well as Roe (US Patent publication No. 2004/0097883 A1) (Hereafter, Roe).

With regards to claim 1-9, Burroughs, Balkwill and Roe disclose (figures 1-15 and figures 1-11, figures 1-18, respectively) a medication dispensing apparatus comprising: a housing; an axially extending drive member rotatably and axially fixed within said housing during dose preparing, and rotatably fixed and axially movable in a distal direction relative to said housing during dose injecting, said drive member including a threaded shaft; a fluid container defining a medicine-filled reservoir with a movable piston at one end and an outlet at the other end, said piston engagable by said drive

member to be advanced toward said outlet when said drive member is moved distally; a nut threadedly engaged with the drive member shaft to be axially movable relative thereto during rotation of said nut relative to said drive member; a nut driver rotatably and axially shiftable relative to said housing; wherein said nut and said driver include cooperating elements which when engaged rotatably lock together said nut and said driver, and which when disengaged permit relative rotation of said nut and said driver; a guide disposed on one of said driver and said housing; a follower disposed on the other of said driver and said housing; wherein said guide and follower cooperate to promote a user moving said driver relative to said housing along a travel path that operates the apparatus, said travel path including a dose preparing section and a dose injecting section, said dose preparing section including a reset segment, a nut engaging segment, and a nut rotating segment connected in sequence, and wherein said injecting section connects said nut rotating segment with said reset segment; wherein said cooperating elements of said nut and said driver are disengaged when said driver is disposed in said reset segment; wherein said cooperating elements of said nut and said driver become engaged when said driver is shifted through said nut engaging segment from said reset segment to said nut rotating segment; wherein the engagement of said cooperating elements of said nut and said driver cause said nut to screw proximally along said threaded shaft when said driver is shifted through said nut rotating segment from said nut engaging segment to said injecting section; wherein when said driver is shifted through said injecting section from said nut rotating segment to said reset segment, said nut and said drive member are shifted in the distal direction

to axially advance said fluid container piston to dispense medicine from said outlet, and said cooperating elements of said nut and said driver become disengaged; and said guide including a hard stop for said follower to define an end of said reset segment of said driver travel path, and said hard stop when abutted by said follower rotationally aligns said driver with said nut engaging segment of said travel path (see Burroughs columns 5 and 6).

With regard to claim 2 Burroughs discloses the medication dispensing apparatus of claim 1 and further discloses (columns 5 and 6) wherein said nut engaging segment and said dose injecting section of said travel path are oriented in the axial direction.

With regard to claim 3 Burroughs discloses the medication dispensing apparatus of claim 1 and further discloses (columns 5 and 6) wherein said reset segment of said travel path is oriented generally transverse to said axial direction.

With regard to claim 4 Burroughs discloses the medication dispensing apparatus of claim 1 and further discloses (columns 5 and 6) wherein said nut rotating segment of said travel path is helically oriented.

With regard to claim 5 Burroughs discloses the medication dispensing apparatus of claim 1 and further discloses (columns 5 and 6) wherein said travel path involves both 360 degrees of rotation of said driver and an equal amount of distal and proximal travel of said driver, whereby said driver, at the end of an injection, has the same axial position and same rotational position as at the end of the prior injection, and wherein said guide includes a second hard stop for said follower to define a second end of said

reset segment of said driver travel path, which second hard stop prevents rotation of said driver in one direction after the end of the injection by abutment by said follower.

With regard to claim 6 Burroughs discloses the medication dispensing apparatus of claim 1 and further discloses (columns 5 and 6) wherein along said injection section of said travel path, said guide comprises first and second surfaces that define a channel in which said follower is slidable, said surfaces during injecting serving as physical stops to prevent rotation of said nut driver by abutment by said follower until an injection is complete, thereby limiting misuse of the apparatus.

With regard to claim 7 Burroughs discloses the medication dispensing apparatus of claim 6 and further discloses (columns 5 and 6) wherein along said nut rotating segment of said travel path, said guide comprises third and fourth surfaces that define a channel in which said follower is slidable, said third surface providing a distal barrier during nut rotating that prevents distal plunging of said driver by abutment by said follower until said follower passes from said nut engaging segment to said injecting section, thereby limiting misuse of the apparatus.

With regard to claim 8 Burroughs discloses the medication dispensing apparatus of claim 1 and further discloses (columns 5 and 6) wherein said follower comprises an outward projection formed on said driver, said outward projection being radially fixed at all times during pen use.

With regard to claim 9 Burroughs discloses the medication dispensing apparatus of claim 8 and further discloses (columns 5 and 6) wherein said guide comprises a

projecting rib formed on said housing and that extends continuously around an interior surface of said housing.

Conclusion

References considered pertinent to Applicants' disclosure are listed on form PTO-892. All references listed on form PTO-892 are cited in their entirety.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Anderson whose telephone number is (571) 272-2764. The examiner can normally be reached on M-F 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael J Anderson
Examiner
Art Unit 3767

MJA
10/29/2007

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons